

TEXTURED BONE ALLOGRAFT, METHOD OF MAKING AND USING SAME

RELATED APPLICATION

This application claims the benefit of the filing date of October 20, 1997, for related, copending, Provisional United States Patent Application Serial No: 60/062,823, hereby incorporated herein in its entirety.

FIELD OF THE INVENTION

The present invention is directed to a textured bone allograft for implantation in a patient, having one or more textured bone surfaces, and methods of making and using the textured bone graft. The textured surface preferably includes a plurality of closely spaced discrete or continuous protrusions. The textured bone allograft is useful for repairing bone defects caused by congenital anomaly, disease, or trauma. The present textured bone allograft promotes the growth of patient bone at an implantation site by promoting osteoinductivity and cellularization, provides added stability and mechanical strength, and does not shift, extrude or rotate, after implantation.

BACKGROUND OF THE INVENTION

In the field of bone grafts, small cut bone grafts and essentially intact bone grafts are implanted at a site in a patient. The success or failure of a bone graft depends on whether the bone graft remains at the implant site, is cellularized, and whether it can withstand the mechanical load.

In spinal surgery, there are two primary indications for use of allograft bone: (1) when there is insufficient available autograft bone, and (2) in spinal fusion procedures when a structural element

in needed. Typically, bone grafts are affixed at an implant site by fusion. Bone grafts for spinal applications often fail because they are extruded from the implantation site due to shifting, rotation, and slippage of the graft, are not cellularized, or fail mechanically. The present invention solves the problem of graft failure by providing a textured bone allograft which promotes the ingrowth of patient bone at an implantation site by promoting osteoinductivity and cellularization, provides added stability and mechanical strength, and does not shift, extrude or rotate, after implantation.

SUMMARY OF THE INVENTION

The present invention is directed to a textured bone allograft for repairing bone defects caused by congenital anomaly, disease, or trauma, including for example, for restoring vertical support of the anterior column. The present textured bone allografts can be used as structural allografts placed anteriorly in the spine as interbody grafts or as strut grafts spanning multiple segments. Posterior textured bone allografts can be used to supplement autologous bone for spinal fusions in patients who lack sufficient host bone and to avoid significant donor site morbidity. The present inventors have surprisingly discovered that providing a textured bone graft results in improved graft stability and osteoinductivity, without a decrease in mechanical strength.

The present invention is directed to a textured bone allograft having a plurality of closely spaced protrusions.

The present invention is directed to a textured bone allograft having a plurality of closely spaced protrusions where the protrusions are continuous, discrete, or a combination thereof.

The present invention is further directed to a textured bone allograft where the shape of the protrusions include: irregular; pyramidal; cuboidal; cylindrical; conical; and rectangular.

The present invention is directed to a textured bone allograft having a plurality of closely spaced protrusions where the cross-section of a continuous or discrete protrusion may be of any shape including for example: irregular; rectangular; square; oval; round; triangular; trapezoidal; and a regular or irregular curve; or any combination thereof.

The present invention is also directed to a textured bone allograft where the protrusions provided on one or more cut surfaces of the bone allograft are from 0.1 to 5.00 mm in height, preferably .3 to 3.0 mm in height, and most preferably .5 to 1.5 mm in height.

The present invention is directed to a textured bone allograft having a plurality of discrete protrusions on one or more cut surfaces where the protrusions are sized to be in the range of from about 0.5 to about 10.0 mm in length; 0.5 to about 10.0 mm in width and 0.1 to about 5.0 mm in height.

The present invention is directed to a textured bone allograft having a plurality of discrete protrusions on one or more cut surfaces where the protrusions are sized to be in the range of from about 1.5 to about 5.0 mm in length; 1.5 to about 5.0 mm in width and 0.5 to about 2.0 mm in height.

The present invention is directed to a textured bone allograft including textured fibular wedges; textured humeral wedges; textured femoral wedges; textured tibial wedges; textured fibular trapezoid wedges; textured humeral trapezoid wedges; textured femoral trapezoid wedges; textured fibular shafts; textured humeral shafts; and textured femoral shafts.

The present invention is also directed to a textured bone allograft having a plurality of protrusions where the protrusions are perpendicular to one or more cut surfaces of the allograft.

The present invention is directed to a textured bone allograft where the plurality of protrusions are located on at least one entire cut surface of the bone allograft.

The present invention is directed to a textured bone allograft where the plurality of protrusions are dimensioned to promote ingrowth of patient bone through increased surface area, at an implantation site.

The present invention is further directed to a textured bone allograft including a plurality of closely spaced protrusions provided on one or more surfaces of the bone allograft.

The present invention is directed to a textured bone allograft where the plurality of continuous protrusions include a plurality of protruding, continuous, concentric rings.

The present invention is further directed to a method of restoring vertical support of the anterior vertebral column by implanting the present textured bone allograft.

The present invention is also directed to a method of making a textured bone allograft by providing the bone allograft with a plurality of closely spaced protrusions on the allograft cut surfaces.

The present invention is further directed to a method for making a textured bone allograft by milling grooves into one or more cut surfaces of the bone allograft to form a plurality of closely spaced protrusions.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1. Figure 1 illustrates a bone allograft ring implant having a textured upper and lower surface which includes a plurality of closely spaced pyramidal shaped protrusions provided over each entire cut surface of the ring, the protrusions being provided perpendicular to the cut surfaces of the bone allograft.

Fig. 1A is a perspective view; Fig. 1B is a upper planer view; and Fig. 1C is a cross-sectional view.

Figure 2. Figure 2 illustrates a bone allograft ring implant having a textured upper and lower surface which includes a plurality of closely spaced, continuous linear protrusions having a “▲” shape provided over each entire cut surface of the ring implant, the linear protrusions being provided perpendicular to the cut surfaces of the bone.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

I. Definitions:

The below definitions serve to provide a clear and consistent understanding of the specification and claims, including the scope to be given such terms.

Bone Allograft. By the term “bone allograft” is intended for the purposes of the present invention, bone including cortical and/or cancellous bone, recovered from a cadaver and processed for implantation into a living patient including for example: fibular wedges; humeral wedges; tibial wedges; fibular trapezoid wedges; humeral trapezoid wedges; femoral trapezoid wedges; fibular shafts and rings; humeral shafts and rings; and femoral shafts and rings; and essentially intact bone grafts including for example proximal and distal femur, femoral head; and small cut bone grafts including for example cancellous cubes, iliac crest wedges, and Cloward dowels.

Closely Spaced. By the term “closely spaced” is intended for the purposes of the present invention, protrusions (discrete or continuous) which are in close proximity to each other. Preferably the protrusions are spaced no more than 3.0mm apart (i.e. the distance between the edges of two

adjacent protrusions), more preferably no more than 2.0mm apart, even more preferably no more than 1.5mm apart, and most preferably about 0.5mm apart

Continuous Protrusion. By the term "continuous protrusion" is intended for the purposes of the present invention, a protrusion whose length continues substantially uninterrupted, including for example a linear or curved protrusion whose length is at least three times greater than its width, preferably at least five times greater, and includes for example a continuous, protruding concentric ring, and a continuous linear protrusion, for example, as illustrated in Fig 2. Each continuous protrusion may or may not be distinct from another continuous protrusion.

Discrete Protrusion. By the term "discrete protrusion" is intended for the purposes of the present invention, a protrusion which is discontinuous, i.e. which has a distinct length and width, where each discrete protrusion is separate and distinct from every other discrete protrusion, for example, as illustrated in Fig.1, and includes for example a protrusion whose length is less than three times its width, preferably less than twice its width and more preferably a protrusion whose length is about equal to its width.

Mechanical Strength. By the term "mechanical strength" is intended for the purposes of the present invention, the ability of a bone allograft to withstand mechanical loads at an implant site without failing.

Osteoinductivity. By the term "osteoinductivity" is intended for the purposes of the present invention, the ability to promote bone growth.

Protrusion. By the term "protrusion" is intended for the purposes of the present invention, an irregularity in a surface of a bone allograft having a height of from 0.1 to 5.00 mm, preferably 0.3 to 3.0 mm, and most preferably 0.5 to 1.5 mm. The protrusions can be discrete, continuous, or a

Station	Time	Latitude	Longitude	Altitude	Temperature	Humidity	Wind	Pressure	Clouds	Visibility	Remarks
1	0800	34° 15' N	121° 05' E	1000	15.0	85	10	1010	100	10	Clear
2	0900	34° 30' N	121° 15' E	1000	15.5	85	10	1010	100	10	Clear
3	1000	34° 45' N	121° 25' E	1000	16.0	85	10	1010	100	10	Clear
4	1100	35° 00' N	121° 35' E	1000	16.5	85	10	1010	100	10	Clear
5	1200	35° 15' N	121° 45' E	1000	17.0	85	10	1010	100	10	Clear
6	1300	35° 30' N	121° 55' E	1000	17.5	85	10	1010	100	10	Clear
7	1400	35° 45' N	122° 05' E	1000	18.0	85	10	1010	100	10	Clear
8	1500	36° 00' N	122° 15' E	1000	18.5	85	10	1010	100	10	Clear
9	1600	36° 15' N	122° 25' E	1000	19.0	85	10	1010	100	10	Clear
10	1700	36° 30' N	122° 35' E	1000	19.5	85	10	1010	100	10	Clear
11	1800	36° 45' N	122° 45' E	1000	20.0	85	10	1010	100	10	Clear
12	1900	37° 00' N	122° 55' E	1000	20.5	85	10	1010	100	10	Clear
13	2000	37° 15' N	123° 05' E	1000	21.0	85	10	1010	100	10	Clear
14	2100	37° 30' N	123° 15' E	1000	21.5	85	10	1010	100	10	Clear
15	2200	37° 45' N	123° 25' E	1000	22.0	85	10	1010	100	10	Clear
16	2300	38° 00' N	123° 35' E	1000	22.5	85	10	1010	100	10	Clear
17	0000	38° 15' N	123° 45' E	1000	23.0	85	10	1010	100	10	Clear
18	0100	38° 30' N	123° 55' E	1000	23.5	85	10	1010	100	10	Clear
19	0200	38° 45' N	124° 05' E	1000	24.0	85	10	1010	100	10	Clear
20	0300	39° 00' N	124° 15' E	1000	24.5	85	10	1010	100	10	Clear
21	0400	39° 15' N	124° 25' E	1000	25.0	85	10	1010	100	10	Clear
22	0500	39° 30' N	124° 35' E	1000	25.5	85	10	1010	100	10	Clear
23	0600	39° 45' N	124° 45' E	1000	26.0	85	10	1010	100	10	Clear
24	0700	40° 00' N	124° 55' E	1000	26.5	85	10	1010	100	10	Clear

Stress. By the term “stress” is intended for the purposes of the present invention, load per unit cross-sectional area.

Textured Bone Allograft. By the term “textured bone allograft” is intended for the purposes of the present invention, a bone allograft having one or more textured surfaces provided on the surface of a bone allograft where the surface of the bone allograft can be any surface including a natural surface and/or a cut surface. The textured surface preferably includes a plurality of protrusions provided on the surface, the protrusions of a shape including for example, irregular; pyramidal; conical; cuboidal; rectangular; trapezoidal; curved; and cylindrical; or any combination thereof. The protrusions can be discrete (for example, as illustrated in Fig. 1), or continuous (for example, continuous linear, as illustrated in Fig. 2).

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II Description of How to Make and Use a Preferred Embodiment of the Present Textured Bone Allograft

The present bone allograft provides a textured surface which increases stability of the graft at an implant site and promotes the ingrowth of patient bone, while providing excellent mechanical strength.

The textured surface includes a plurality of protrusions. The protrusions can be formed over an entire surface of a bone allograft or over a portion of a surface, for example over the entire natural and cut surfaces, over a portion of the natural and/or cut surfaces, or over the entire cut surface. The plurality of protrusions can be formed on the surface in any number of ways well known to those of ordinary skill in the art to which the present invention pertains, including for example mechanical and/or chemical methods, including for example, by forming a series of parallel linear or curved grooves. The bone allograft protrusions illustrated in Fig. 1 are formed by milling a first set of parallel linear grooves on the cut surface of the allograft followed by turning the allograft and forming a second set of parallel grooves at an angle to the first series, for example, at a 90° angle. Milling is preferably achieved, by for example: running the graft over a milling tool which includes a plurality of closely spaced blades which can be adjusted to achieve a desired height and width, and then turning the graft at, for example, a 90° angle and again running it over the milling tool to produce the discrete protrusions illustrated in Fig. 1. Milling can also be achieved using for example a routing or dremel tool, a laser, and masking and acid etching.

Other protrusions, for example concentric rings or other curved or irregular, or regular protrusions can be provided by attaching a drill bit having a blade corresponding to the protrusion pattern desired where the blade is appropriately sized to provide a desired protrusion width, length,

and height, to a drill and drilling the desired surface of the bone to achieve the desired textured surface. One of ordinary skill in the art can readily design and produce, or select, and employ an appropriate milling tool to achieve a desired textured surface on a bone allograft, without undue experimentation.

Preferably, the protrusions (discrete, continuous, or a combination thereof) present on one or more surfaces of the present allograft are closely spaced, preferably from about 0.0 to 3.0 mm apart, preferably 0.1 to 2.0 mm apart, more preferably about 0.2 to 1.5 mm apart, and most preferably about 0.5 mm apart, (that is, there is preferably a distance of from 0.0 to 3.0 mm between the edges of two adjacent protrusions).

III. Procurement and Processing of Allograft Bone Tissue

Allograft tissue is obtained from a cadaver, and processed under strict aseptic conditions in certified clean room operating suites. The bone tissue is preferably processed to remove all soft tissue, including marrow and blood, to produce a cleaned bone graft. Suitable processing methods are well known to those skilled in the art and can be readily selected and employed by those of ordinary skill in the art without undue experimentation. Suitable methods include the methods disclosed in, for example, United States Patent No.: 5,556,379. After processing, the cleaned grafts are packaged under sterile conditions and stored for latter processing into the present textured bone allograft, or immediately processed into the present textured bone allograft followed by appropriate packaging. The use of fresh-frozen and/or freeze-dried, bone allografts are preferred.

IV. Textured Bone Allografts

The present textured bone allografts are useful in spinal applications including restoration of anterior column support and can be used from either an anterior or posterior approach. Textured allografts suitable for placement in cervical, thoracic and lumbar interbody fusions preferably include textured wedges including: fibular textured allograft wedges having a diameter of from 8 to 16mm, preferably 10 to 14mm, and a height of from 3 to 16mm, preferably from 5 to 14mm; humeral textured allograft wedges having a diameter of from 17 to 24mm, preferably 19 to 22mm, and a height of from 4 to 16mm, preferably from 6 to 14mm; tibial textured allograft wedges having a diameter of from 20 to 30mm, preferably 23 to 27mm, and a height of from 4 to 18mm, preferably from 6 to 16mm; and femoral textured allograft wedges having a diameter of from 20 to 30mm, preferably 23 to 27mm, and a height of from 4 to 18mm, preferably from 6 to 16mm.

Textured allografts suitable for use in restoring lordosis in the lumbar spine include textured trapezoid shaped wedges, including for example: fibular textured trapezoid wedges having a diameter of from 8 to 16mm, preferably 10 to 14mm, and a height of from 3mm x 6mm to 13mm x 16mm, preferably from 5mm x 8mm to 11mm x 14mm; humeral textured trapezoid wedges having a diameter of from 17 to 24mm, preferably 19 to 22mm, and a height of from 4mm x 12mm to 19mm x 22mm, preferably from 11mm x 14mm to 17mm x 20mm; and femoral textured trapezoid wedges having a diameter of from 21 to 29mm, preferably 23 to 27mm, and a height of from 4mm x 12mm to 19mm x 22mm, preferably from 11mm x 14mm to 17mm x 20mm.

Textured allografts suitable for addressing large column defects include textured allograft shafts, including for example: fibular textured shafts having a diameter of from 8 to 16mm, preferably 10 to 14mm, and a height of from 10 to 60mm, preferably from 20 to 50mm; humeral

textured shafts having a diameter of from 17 to 24mm, preferably 19 to 22mm, and a height of from 10 to 60mm, preferably from 20 to 50mm; and femoral textured shafts having a diameter of from 21 to 29mm, preferably 23 to 27mm, and a height of from 30 to 80mm, preferably from 40 to 70mm.

The present textured bone allografts are preferably textured with a plurality of closely spaced protrusions over their entire opposing cut surfaces. Other suitable grafts for cervical fusion include textured iliac crest bone allografts.

V. Surgical Implantation and Indications

The present textured bone allograft is useful for implantation in patients suffering from defects caused by congenital anomaly, disease, or trauma, including for example, spine fractures; deformity, e.g. kyphotic deformities, e.g. posttraumatic kyphosis; postlaminectomy kyphosis, junctional kyphosis, and Scheuermann's kyphosis; scoliosis, e.g. neuromuscular scoliosis, adult scoliosis, paralytic scoliosis, congenital and syndromic scoliosis; and cervical neck pain. Surgical methods for correcting degenerative conditions, for example in the lumbar spine, include decompression (excision of disc material, hypertrophied bone, or ligament along with fusion, or fusion alone.

An anterior or posterior surgical approach can be used. The choice of approach is dictated by the site of primary pathology. Pathology that involves vertebral bodies is best approached anteriorly through the thorax, abdomen or flank. Pathology involving posterior elements are best approached posteriorly for example, through a vertical midline approach or posterior lateral muscle spinning approach.

Those of ordinary skill in the art to which the present invention pertain, e.g. an orthopaedic surgeon, a spinal surgeon, etc., can readily select and employ a particular textured bone allograft, without undue experimentation. Factors to be considered in such selection and employment include: the type of allograft bone, its anatomic site of fusion, and the age of the patient. An ideal graft, for example for use in lumbar interbody fusion, should be: osteoinductive, non-immunogenic, provide immediate mechanical stability, and be appropriately sized and shaped for the particular application/patient. Indications, diagnostic criteria, graft selection and surgical technique, are factors that can be readily selected, optimized and employed by those of ordinary skill in the art without undue experimentation, and are discussed in: Master Techniques in Orthopaedic Surgery, *The Spine*, edited by Bradford, David S., Lippincott-Raven, ISBN 0-7817-0033-7, Philadelphia, PA, (1997), hereby incorporated herein by reference in its entirety.

It is to be understood, however, that the scope of the present invention is not to be limited to the specific embodiments described above. The invention may be practiced other than as particularly described and still be within the scope of the accompanying claims.